

System Overview

Intended Use

The UniCel DxH 800 Analyzer is a quantitative, automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The UniCel DxH 800 Analyzer provides a:

- Complete Blood Count (CBC), Leukocyte 5 Part Differential (Diff), Reticulocyte (Retic) and Nucleated Red Blood Cell (NRBC) on whole blood
- Total Nucleated Count (TNC) and Red Cell Count (RBC) on Body Fluids (cerebrospinal, serous and synovial) (BF)

Parameters

The system determines these hematologic parameters:

WBC	White Blood Cell count
UWBC	Uncorrected White Blood Cell count
RBC	Red Blood Cell count (for Whole Blood and Body Fluids)
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Cell Distribution Width
RDW-SD	Red Cell Distribution Width Standard Deviation (SD)
PLT	Platelet count
MPV	Mean Platelet Volume
NE	Neutrophil percent
LY	Lymphocyte percent
MO	Monocyte percent
EO	Eosinophil percent

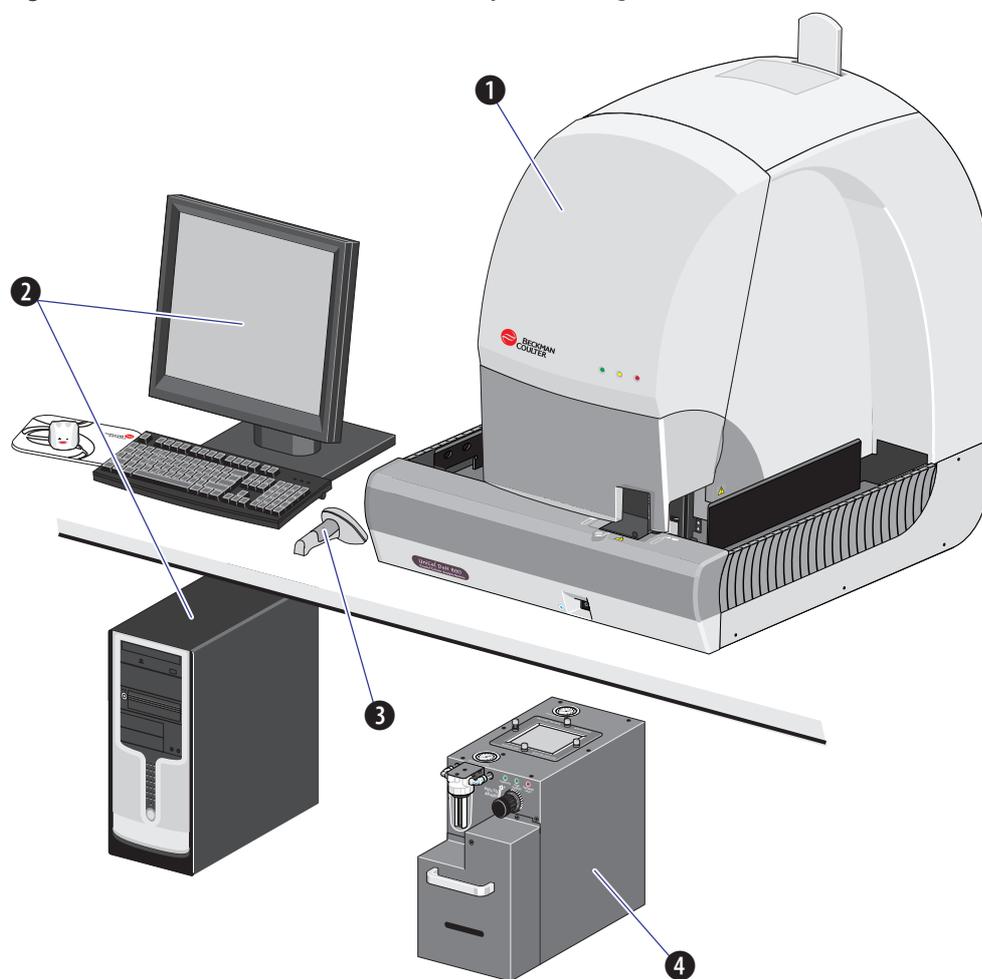
1.3.5. Matuojami visi nurodyti parametrai

System Overview
Intended Use

BA	Basophil percent
NE#	Neutrophil absolute number
LY#	Lymphocyte absolute number
MO#	Monocyte absolute number
EO#	Eosinophil absolute number
BA#	Basophil absolute number
NRBC	Nucleated Red Blood Cell percent
NRBC#	Nucleated Red Blood Cell absolute number
RET	Reticulocyte percent
RET#	Reticulocyte absolute number
MRV	Mean Reticulocyte Volume
IRF	Immature Reticulocyte Fraction
TNC	Total Nucleated Cell (Body Fluids)

UniCel DxH 800 SYSTEM

Figure 1.1 DxH 800 SYSTEM (SPM, PSM, and System Manager)



Component	Function
1. Specimen Processing Module (SPM)	Processes patient specimens and sends raw data to the System Manager.
2. System Manager	<ul style="list-style-type: none"> Controls processes, such as analysis and diagnostic procedures. Produces test results. Manages data, such as test ordering, results review, results release, quality control, LIS interface, logging, and report generation. Includes an LCD flat panel monitor with touch screen capability, a computer with CD/DVD RW drive running Microsoft® Windows® XP Professional operating system, the DxH 800 software, a standard keyboard, and an optical mouse.
3. Hand-held bar-code scanner	Reads bar-code labels on specimen tubes.
4. Pneumatic Supply Module (PSM)	Supplies vacuum and pressure to the SPM.

Hardware

Overview

The DxH 800 System includes a Specimen Processing Module (SPM), a Pneumatic Supply Module (PSM), and a System Manager, precisely integrated to provide process control, data consolidation, and cassette or single-tube delivery of specimens. See Figure 1.1.

Inter-Unit Connections

Power and Signal Cables

Figure 1.2 shows the warning label at the back of the SPM that alerts you to the possible presence of AC Voltages.



To avoid electric shock, use caution as AC Voltages may be present.

Figure 1.2 Power Connection

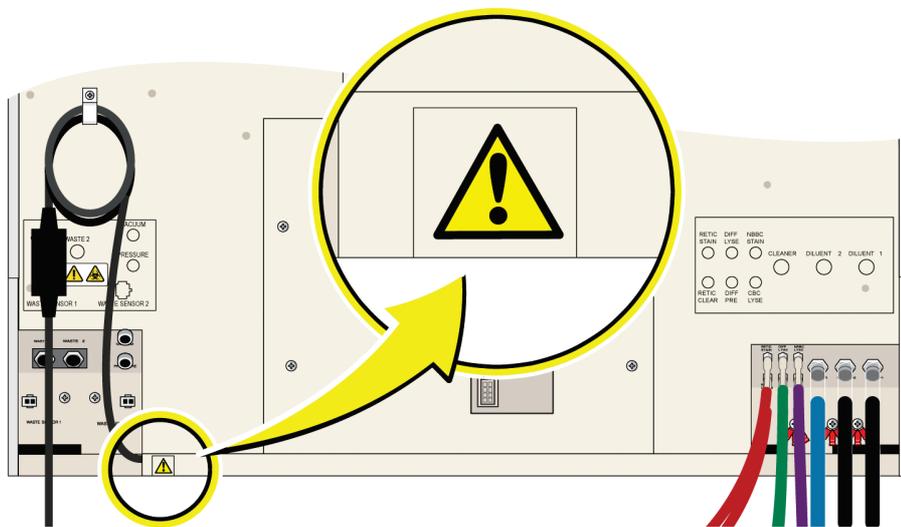
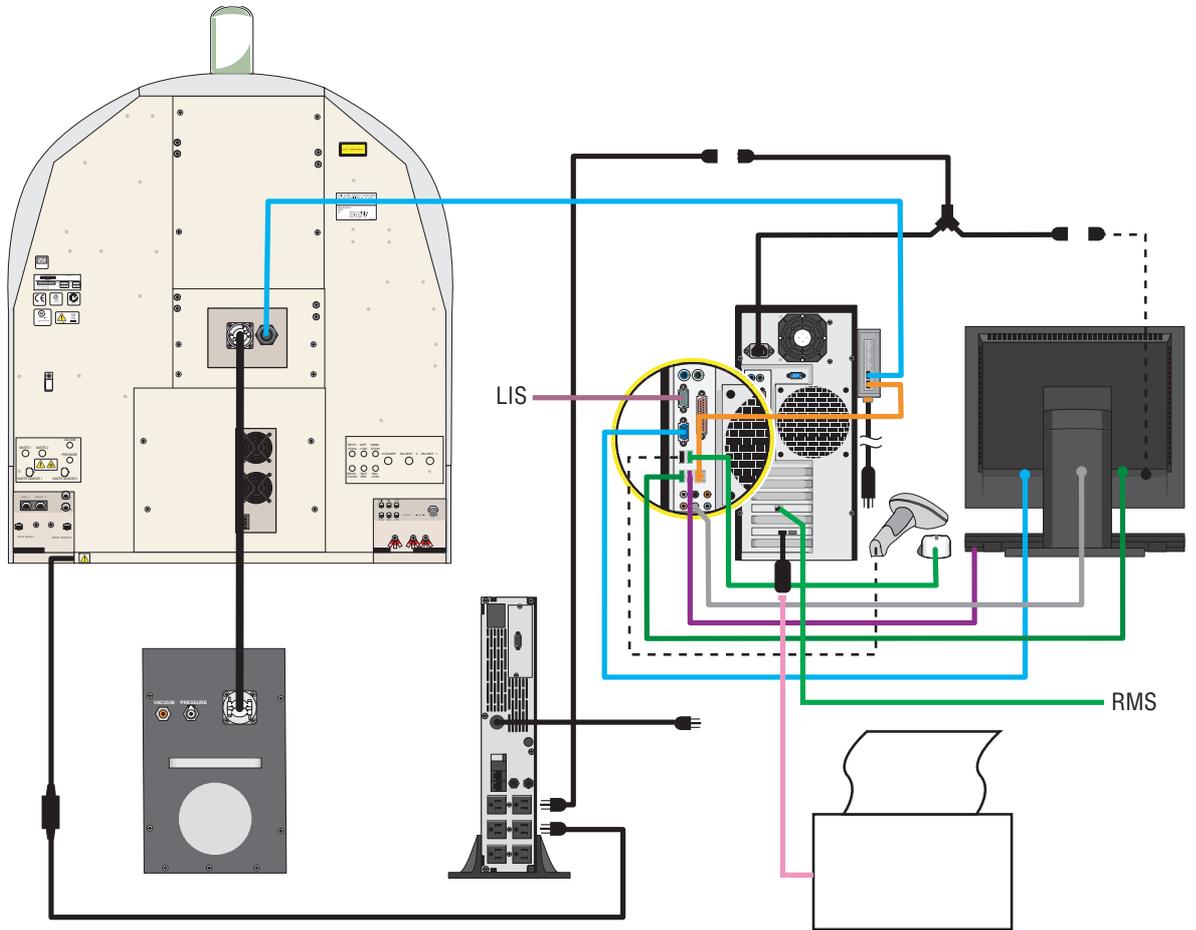


Figure 1.3 shows the inter-unit connections of the power and signal cables that are supplied with the instrument. Your Beckman Coulter Representative makes these connections when installing the instrument.

NOTE The colors used in Figure 1.3 are for illustration only, they are representative of the colors of the actual connections.

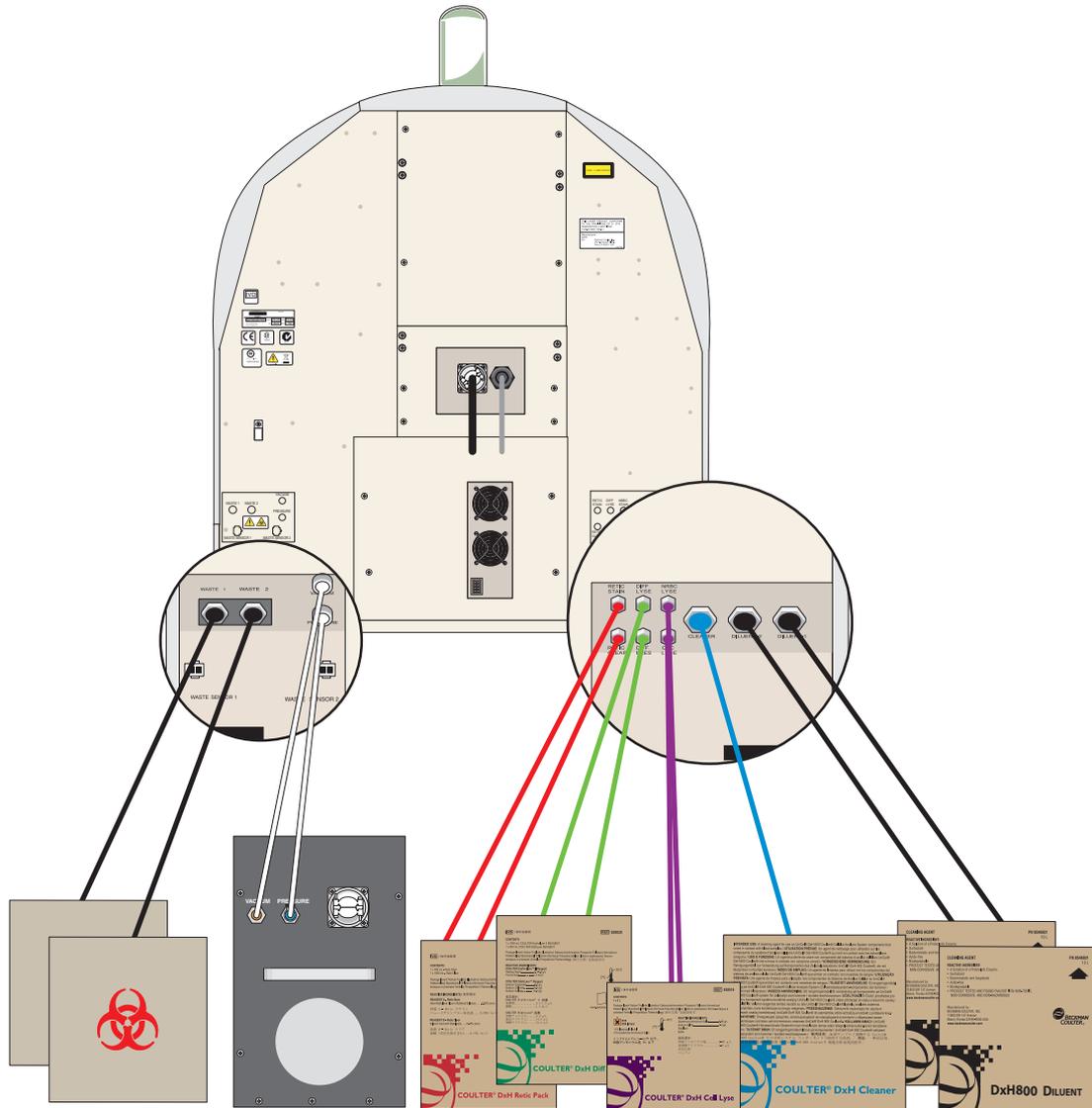
Figure 1.3 Interunit Power and Signal Cable Connections



The figure below shows the connections between the SPM and the consumable reagents and waste containers.

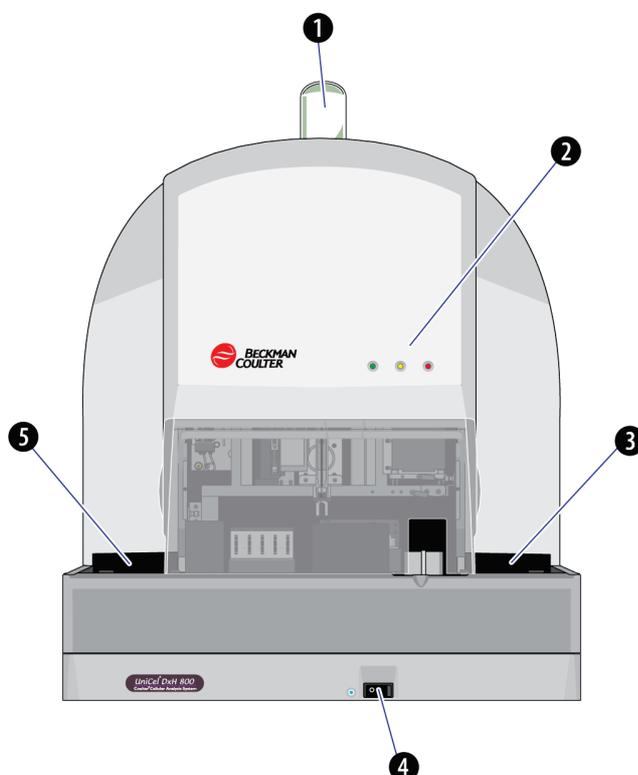
NOTE The colors in Figure 1.4 show inter-related tubing and packing connections. Refer to [Figure 9.3, Supplies Screen](#) for additional information on the correlation of these colors to supply status graphics on the Supplies Screen. Refer to Replacing Reagents for information on replacing the reagents.

Figure 1.4 SPM Consumable Connections



Front View of the SPM

Figure 1.5 Front View of SPM



The components called out in the figure above are as follows:

- | | |
|---------------------------------------|---|
| 1. Beacon | The light at the top of the SPM is a Beacon to visually alert you to conditions that require attention. |
| 2. Status Lights | The Status Lights on the front of the SPM are green, yellow and red LED lights. |
| 3. Input Buffer | Place specimen cassettes here. |
| 4. Power Button with ON/OFF Indicator | The power button allows you to turn the SPM on and off. |
| 5. Output Buffer | The area where you remove cassettes that have been processed. |

Functional Modules

The SPM is made up of the following functional modules.

- Specimen Transport Module (STM)
- Sample Aspiration Module (SAM)
- VCSn Module
- CBC Module
- Common Services

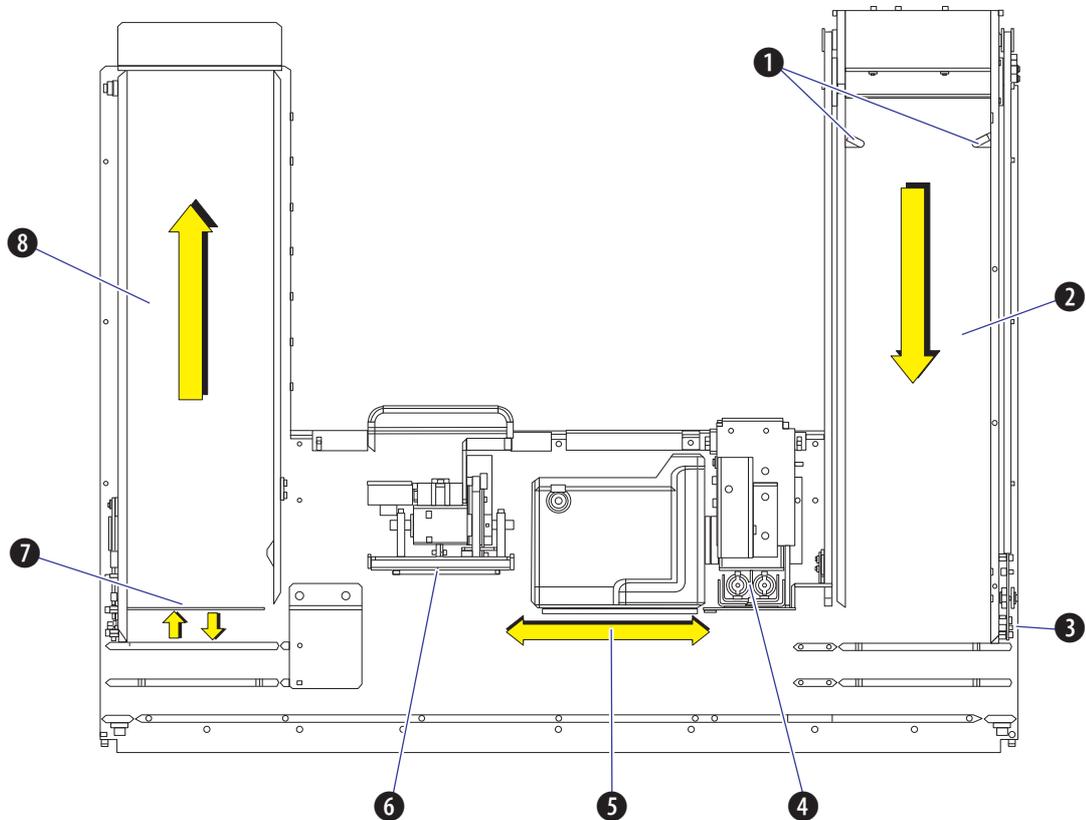
Specimen Transport Module

The STM automatically transports specimens. It delivers closed-vial and open-vial specimens accommodating a wide range of specimen tubes. The STM supports the following:

- Operator loading and unloading of specimens
- Transport and queuing of specimens
- Mixing and presentation of specimens

The STM uses a Magnetic Transport System to move cassettes containing specimens. Show me specimen transport.

Figure 1.6 STM Top Level View



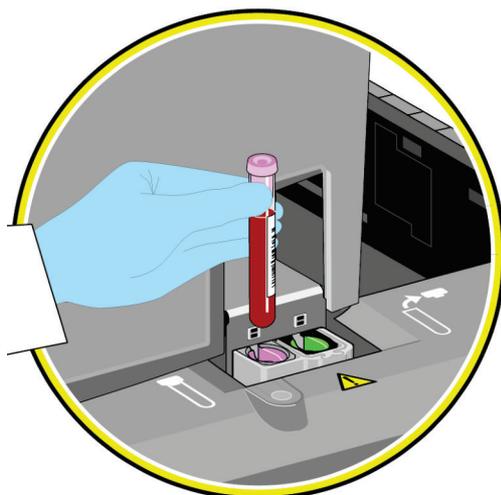
The components called out in the figure above are as follows:

1. Input Buffer Pushers
2. Input Buffer
3. STAT Cassette Position
4. Single-tube Presentation Station
5. Pending Buffer
6. Mix Station
7. Output Buffer Pusher
8. Output Buffer

Input Buffer

The input buffer is where you place specimen cassettes. The capacity is 20 cassettes. The STM magnetically sweeps the cassettes forward for transport to the mixing station.

Single-tube Station with Cradle



The Single-tube Station cradle accepts many sizes of tubes. The right position is optimized for minimal dead volume sampling from the open vial tubes from 7 to 13 mm in diameter. The left position accepts open and closed vials from 12 to 16 mm in diameter. A fixed bar-code reader reads the bar-code labels at or near the depression on the cover in front of the Single-tube Station.

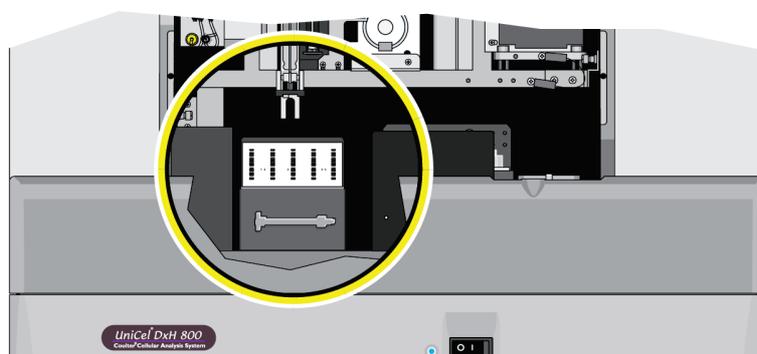
At the right position, the minimum tube height required is 30 mm. The left position minimum tube height is 55 mm (measured from under the cap). The maximum height for both sides is 107 mm (with the cap if present).

Pending Buffer

The pending buffer is a temporary holding place for a single cassette while it is in transit, or waiting for repeat or reflex testing. A cassette in the pending buffer blocks the path of a cassette from the input buffer to the mixer wall. Thus, a cassette in the pending buffer has higher priority than cassettes in the input buffer and must be cleared out before a cassette can exit the input buffer.

Mix Station and Aspiration Probe

Figure 1.7 Mix Station and Aspiration Probe



The Mix Station is the area where the Specimen ID is read; the specimen is mixed by rocking 11 times; and, the sample is aspirated by the aspiration probe. Additionally, the specimens are mixed four times between aspirations. Show me mixing by rocking.

Output Buffer

Upon completion of their operation, cassettes are transported to the output buffer to await their removal. The output buffer is an output area capable of holding up to 20 cassettes.

Sample Aspiration Module **1.3.8. 1. Tyrimas atliekamas iš uždarų ir atvirų mėgintuvėlių.**

The SAM aspirates from capped specimen tubes (presented via Cassette or Single-tube presentation) or open vials (Single-tube presentation). Body fluids are presented via Single-tube, while whole bloods can be presented in either presentation mode. The identification and integrity of samples are verified prior to delivery and transfer to the analytical modules within the system. The SAM design provides for two methods of sample delivery: sample segmentation and sample dispensing. In sample segmentation, aspirated sample is transferred through the BSV where it is segmented for whole blood CBC and body fluid. In sample dispensing, whole blood sample segments are then dispensed via the aspiration probe into the mixing chambers on the Air Mix Temperature Control Module (AMTC) for the WBC differential, NRBC and reticulocyte analyses.

Aspiration Syringe

The aspiration syringe controls the volume and rate of sample aspiration. It is precisely controlled by a stepper-motor driven aspiration syringe.

Blood Detectors

Two blood detectors are located one on each side of the BSV. The front detector is located between the top of the aspiration probe and the front port of the BSV. The rear detector is located between the rear BSV port and the aspiration syringe. The blood detectors monitor the passage of the sample through the aspiration process and can differentiate between blood, air, and diluent.

BSV

When the sample reaches the BSV it is segmented for CBC analysis within the CBC module.

Aspiration Probe

The aspiration probe allows for sampling from both closed and open specimen tubes. The aspiration probe pierces through the cap to allow sample aspiration.

Show me tube piercing.

The aspiration probe moves depending on the tube presentation position. Once sample has been aspirated it can move to the mixing chambers to allow sample to be dispensed for other analyses.

1.2.8. 3. Hematologinis analizatorius turi ėminių barkodų skenavimą

Bar-code Reader

The 2D compatible digital barcode reader (camera) does the following:

- Provides for positive identification for all specimen tube IDs in the form of an image.
- Reads the cassette and specimen IDs twice prior to aspiration. Each read includes a minimum of 10 passes.
- Supports symbologies as small as 7 mil and larger and includes Code 128, Codabar, NW7, Code 39 and Interleave 2 of 5.
- Reads a maximum number of 22 characters plus checksum.

VCSn Module

The VCSn Module provides the physical processing elements necessary for the Differential, NRBC, and Retic sample preparation and subsequent measurement. The VCSn Module includes the Distribution Valve (DV), Air Mix Temperature Control (AMTC) module, Multi-transducer Module (MTM) and their associated electronic and fluidics. Samples prepared at the AMTC are delivered to the MTM where the sample detection occurs.

NOTE The VCSn module is described in more detail in the Operation Principles chapter of this manual.

CBC Module

The CBC Assembly provides the physical processing elements necessary for CBC sample conditioning (combining of reagents and the sample segment, mixing and incubation) and measurement via the aperture bath assemblies, the HGB assembly and the electrical signal conditioning circuits.

NOTE The CBC module is described in more detail in the Operation Principles chapter of this manual.

Common Services

Common Services consist of the Electronic Supply Module, Pneumatic Services and Reagent Services (supply and distribution). Common Services provides and monitors electronic power and supplies and monitors the reagent and waste levels as well as the pressure and vacuum.

Pneumatic Supply Module (PSM)

The Pneumatic Supply Module (PSM) is the source of vacuum and pressure to Common Services.